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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/527,558	03/16/00	PFIRRMANN	R 1194-153

EXAMINER

HM22/1005

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ART UNIT	PAPER NUMBER
1623	3

DATE MAILED: 10/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/527,558	Pfirrmann
Examiner	**Group Art Unit**
Leigh Maier	1623

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-20* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

Howard C. Lee

Howard C. Lee
Primary Examiner
Art Unit 1623

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Status of the Claims

Claims 1-20 are pending.

Priority

Applicant's claim to foreign priority based on British application 971621902, filed July 31, 1997, for this continuation-in-part of US patent application serial number 09/493,797 is acknowledged. However, the British application is directed to the use of taurolidine in the prevention of metastases and does not indicate that the applicant was in possession of the instant invention. The instant claims are considered have benefit US provisional application 60/126,940, filed March 29, 1999.

Specification

A substitute specification including claims is required pursuant to 37 CFR 1.125(a) because the specification and claims appear to a poor quality facsimile copy in which the text is noly marginally legible.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute

specification must be filed under 37 CFR 1.125(b) and must be accompanied by: 1) a statement that the substitute specification contains no new matter; and 2) a marked-up copy showing the amendments to be made via the substitute specification relative to the specification at the time the substitute specification is filed.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Lehner (WO 98/28027).

Lehner discloses the use of taurolidine or taurultam for treating a liquid delivery system for a patient receiving chemotherapy or total parenteral nutrition. (See procedures on pp 9-10) This method involves flushing delivery system with a sterile saline solution of heparin (a known anti-coagulant) followed by filling the system with a solution of taurolidine (known as an anti-microbial *and* an anti-coagulant). The solutions are 0.5 to 3% by weight of taurolidine or 1 to 7.5% by weight of taurultam. (See claim 4.) The delivery system containing the taurolidine solution is then sealed for up to 12 hours. Although the focus of Lehner's disclosure is on reduction of infection and sepsis in liquid delivery systems, the use of these two agents known to have anti-coagulant activity would inherently inhibit thrombosis.

Claims 16-18 and 20 are rejected under 35 U.S.C. 102(b) as anticipated by Reinmuller (US 5,077,281).

Reinmuller discloses the use of taurolidine as an anti-coagulant in addition to its previously known use as an anti-microbial. ~~Although~~ A solution of taurolidine and another anti-coagulant, such as heparin, is disclosed. (See abstract and col 4, lines 33-36.) The skilled artisan would be motivated to use these agents in combination for the complementary and attenuating functions they exhibit. (See col 4, lines 60-68 and col 5, lines 1-19.) Furthermore, in claims 16 and 20, the anti-coagulant is not specified to be one *other than* taurolidine, and would read upon any solution thereof having the claimed concentration.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lehner (*supra*) in view of Ito et al (5,167,960).

Lehner teaches anti-microbial/anti-thrombotic treatment of liquid delivery systems as discussed above. Lehner does not teach the use of other anti-coagulants besides heparin.

Ito et al teach the use of thromboresistant agents in combination with implantable or extracorporeal devices. Discussed is the different physiological mechanisms and side effects of various anti-coagulants such as heparin, hirudin, and ticlopidine. (See col 1-2)

It would be obvious to one having ordinary skill in the art to choose among known anti-coagulants in carrying out the method of Lehner. It would be within the scope of the skilled practitioner to choose the agent which would be most compatible with the situation at hand.

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reinmuller (*supra*) in view of Ito et al (*supra*).

Reinmuller discloses the use of taurolidine in combinattion with another anti-coagulant, such as heparin, as discussed above.

Ito et al outlines the different physiological mechanisms and side effects of various anti-coagulants such as heparin, hirudin, and ticlopidine, also discussed above.

It would be obvious to one having ordinary skill in the art to choose among known anti-coagulants to combine with taurolidine. It would be within the scope of the skilled practitioner to choose the agent which would be most compatible with the situation at hand.

Examiner's hours, phone & fax numbers and other useful information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525 and e-mail address is Leigh.Maier@uspto.gov (NOTE: ***The U.S PTO does not accept responsibility for the security of e-mail transmissions by the applicant(s).*** Thus, e-mail sent to an examiner should not include confidential information. For further details, see the PTO Internet Usage Policy which has been published in the Federal Register of 21 June 1999, volume 64, number 118.) The examiner can normally be reached on Monday-Friday 8:00 to 4:30 (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Gary Geist (703) 308-1701, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at http://**www.uspto.gov**. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Secure and confidential access to patent application status is now available; see http://www.uspto.gov/ebc/index.html for more information.

Applicant(s) may pay patent maintenance fees, non-filing application fees and maintain USPTO accounts through http://www.uspto.gov/web/offices/ac/comp/fin/clonedefault.htm

Leigh C. Maier
Patent Examiner
September 29, 2000

Howard C. Lee

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Art Unit 1623